IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Thuy P. Beier

Application Number: Not assigned — Group Art Unit: Not assigned

Filed: Concurrently herewith — Examiner: Not assigned

Title: Viral Detection System — Attny. Docket No. TPB-001D

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, applicant hereby requests that the following amendments and remarks be entered into the subject application.

IN THE SPECIFICATION

At page 1, please delete lines 11-13 and insert the following:

-- This application is a divisional of Application No. 09/159,325, filed on September 23, 1998, which claims priority under U.S.C. § 119(e) to Provisional Application No. 60/061,287, filed October 7, 1997. Priority to these applications is hereby claimed under 35 U.S.C. §§ 120 and 121, and each of these applications is hereby incorporated by reference in its entirety.--

IN THE CLAIMS

1. (Amended) A method of detecting the nucleic acid of naturally occurring avian leucosis/sarcoma viruses in egg albumen, wherein said naturally occurring virus is isolated or detected from chicken or egg host that have acquired infection by the wild-type of said virus in nature [at the nucleic acid level in an avian sample], comprising the steps of:

isolating viral RNA from said [avian sample] albumen using β-mercaptoethanol; and

performing RT-PCR.

2. The method of claim 1, wherein said [avian sample] egg albumen is selected from the group consisting of unfertilized chicken egg albumen, fertilized chicken egg albumen, unfertilized egg albumen from an animal of the class *Aves* and fertilized egg albumen from an animal of the class *Aves*.

Please delete claims 3, 4 and 5.

6. A method of determining the subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus [subgroup specificity at the nucleic acid level], including distinguishing between exogenous and endogenous retroviruses, comprising the steps of:

isolating viral RNA [a specimen from an avian sample] from egg albumen using β-mercaptoethanol;

performing RT-PCR; and

sequencing the amplified RT-PCR product, wherein the resulting sequence will determine the subgroup specificity of said virus and distinguish between exogenous and endogenous retrovirus.

7. The method of claim 6, wherein said egg albumen [avian sample] is selected from the group consisting of unfertilized chicken egg albumen, fertilized chicken egg albumen, unfertilized egg albumen from an animal of the class *Aves* and fertilized egg albumen from an animal of the class *Aves*.

Please delete claims 8, 9, 10, 11 and 12.

13. A method of detecting the nucleic acid of naturally occurring avian leucosis/sarcoma viruses in a poultry sample, wherein said naturally occurring virus is isolated or detected from chicken or egg host that have acquired infection by the wild-type of said virus in nature [at the nucleic acid level in a poultry sample], comprising the steps of:

isolating viral RNA from egg albumen of said poultry sample using β-mercaptoethanol; and

performing RT-PCR using an oligonucleotide [of claim 11] having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b).

Please delete claim 14.

15. A method of determining the subgroup specificity of the nucleic acid of naturally occurring avian [leukemia] leucosis/sarcoma virus [subgroup specificity at the nucleic acid level] and distinguishing between exogenous and endogenous retroviruses, comprising the steps of:

obtaining egg albumen from a poultry sample;

isolating viral RNA from said albumen using β-mercaptoethanol;

performing RT-PCR using an oligonucleotide [of claim 11] having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b); and

sequencing the amplified RT-PCR product, wherein the resulting sequence will determine the subgroup specificity of the virus and distinguish between exogenous and endogenous retrovirus.

Please delete claim 16.

Please add new claim 17as follows:

--17. The method of claim 6, wherein the RT-PCR is performed using an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b). --

REMARKS

The cross-references to related applications have been incorporated into the specification in accordance with 37 C.F.R § 1.77(a)(4). No new matter has been introduced. Applicant respectfully requests that the amendments above and remarks below be entered and made of record in the file history of the instant application.

This application is a divisional application of copending application bearing Serial No. 09/159,325. The '325 application was originally filed with 16 claims. The '325 parent application currently consists of amended claims 1, 2, 6, 7, 13, 14, 15, 16 and added claim 17. In the Office Action dated December 29, 2000, the Examiner withdrew all remaining rejections over cited prior art references. The Examiner, however, rejected all pending claims as unpatentable under 35 U.S.C. § 112, ¶ 1 for lack of enablement. The Examiner stated that "the specification, while being enabling or isolating viral RNA from albumen with β-mercaptoethanol ..., does not reasonably provide enablement for isolating viral RNA from albumen with any reagent." (Office Action at 2).

In this preliminary amendment as explained below, claims 1, 2, 6, 7, 13 and 15 have been amended. Claims 3-5, 8-12, 14 and 16 have been deleted. New claim 17 has been added. Claim 1, 2, 6, 7, 13, 15 and 17 are currently pending in the present application.

First, claims 3-5 and 8-12 were deleted and claims 1, 2, 6, 7, 13, 15 and 17 were amended and rewritten, so that the remaining claims are substantially in the same form as they appear in the '325 application. In other words, all the deletions and amendments made to the claims in the '325 application are integrated to the claims in the present application.

Second, claims 14 and 16 were deleted to reflect the fact that Dr. Johnson is not a listed inventor in the present case. New claim 17 also differs from claim 17 in the '325 application to reflect this fact.

Finally, independent claims 1, 6, 13 and 15 have been amended to further recite – using β-mercaptoethanol.-- This amendment addresses the Examiner's enablement rejection under 35 U.S.C. § 112, ¶ 1. Dependent claims 2, 7 and 17 depend on claims 1 or 6, and recited further limitations therefrom. Hence, it is believed that this rejection has been overcome.

A clean version of the pending claims, without the square brackets and underlines, is attached hereto.

Applicant believes that the pending claims in present application are in condition for allowance. Early notice of allowance is earnestly solicited.

No fee is believed due for this amendment.

Respectfully submitted

Date: May 25, 2001

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REMAINING CLAIMS IN PRESENT APPLICATION

1. A method of detecting the nucleic acid of naturally occurring avian leucosis/sarcoma viruses in egg albumen, wherein said naturally occurring virus is isolated or detected from chicken or egg host that have acquired infection by the wild-type of said virus in nature, comprising the steps of:

isolating viral RNA from said albumen using β-mercaptoethanol; and

performing RT-PCR.

2. The method of claim 1, wherein said egg albumen is selected from the group consisting of unfertilized chicken egg albumen, fertilized chicken egg albumen, unfertilized egg albumen from an animal of the class *Aves* and fertilized egg albumen from an animal of the class *Aves*.

6. A method of determining the subgroup specificity of nucleic acid of naturally occurring avian leucosis/sarcoma virus, including distinguishing between exogenous and endogenous retroviruses, comprising the steps of:

isolating viral RNA from egg albumen using β-mercaptoethanol;

performing RT-PCR; and

sequencing the amplified RT-PCR product, wherein the resulting sequence will determine the subgroup specificity of said virus and distinguish between exogenous and endogenous retrovirus.

7. The method of claim 6, wherein said egg albumen is selected from the group consisting of unfertilized chicken egg albumen, fertilized chicken egg albumen, unfertilized egg albumen from an animal of the class *Aves* and fertilized egg albumen from an animal of the class *Aves*.

13. A method of detecting the nucleic acid of naturally occurring avian leucosis/sarcoma viruses in a poultry sample, wherein said naturally occurring virus is isolated or detected from chicken or egg host that have acquired infection by the wild-type of said virus in nature, comprising the steps of:

isolating viral RNA from egg albumen of said poultry sample using β-mercaptoethanol; and

performing RT-PCR using an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b).

15. A method of determining the subgroup specificity of the nucleic acid of naturally occurring avian leucosis/sarcoma virus and distinguishing between exogenous and endogenous retroviruses, comprising the steps of:

obtaining egg albumen from a poultry sample;

isolating viral RNA from said albumen using β-mercaptoethanol;

performing RT-PCR using an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b); and

sequencing the amplified RT-PCR product, wherein the resulting sequence will determine the subgroup specificity of the virus and distinguish between exogenous and endogenous retrovirus.

17. The method of claim 6, wherein the RT-PCR is performed using an oligonucleotide having a sequence at least 95% identical to a sequence selected from the group consisting of: (a) SEQ ID No: 7 and SEQ ID No: 8; (b) a nucleotide sequence encoding the gp^{env} 85 protein; and (c) an oligonucleotide which hybridizes under stringent hybridization conditions to a oligonucleotide defined by (a) or (b).